

(1) *Reuse guidelines.* Voluntary guidelines adopted by the AAMI ("Reuse of Hemodialyzers," second edition). Incorporation by reference of the AAMI's "Reuse of Hemodialyzers," second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.¹ If any changes in "Reuse of Hemodialyzers," second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.

(2) *Procedure for chemical germicides.* To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.

(3) *Surveillance of patient reactions.* In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility—

(i) Takes appropriate blood cultures at the time of a febrile response in a patient; and

(ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.

(b) *Standard: Transducer filters.* To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.

(c) *Standard: Bloodlines.* If the ESRD facility reuses bloodlines, it must—

(1) Limit the reuse of bloodlines to the same patient;

(2) Not reuse bloodlines labeled for "single use only";

(3) Reuse only bloodlines for which the manufacturer's protocol for reuse

has been accepted by the Food and Drug Administration (FDA) pursuant to the premarket notification (section 510(k)) provision of the Food, Drug, and Cosmetic Act; and

(4) Follow the FDA-accepted manufacturer's protocol for reuse of that bloodline.

[52 FR 36935, Oct. 2, 1987, as amended at 55 FR 18335, May 2, 1990; 60 FR 48044, Sept. 18, 1995]

§405.2160 Condition: Affiliation agreement or arrangement.

(a) A renal dialysis facility and a renal dialysis center (see §405.2102(e)(2)) have in effect an affiliation agreement or arrangement with each other, in writing, for the provision of inpatient care and other hospital services.

(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its files documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:

(1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;

(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and

(3) Security and accountability for patients' personal effects are assured.

§405.2161 Condition: Director of a renal dialysis facility or renal dialysis center.

Treatment is under the general supervision of a Director who is a physician. The physician-director need not

¹The publication entitled "Reuse of Hemodialyzers," second edition, 1993, is available for inspection at the HCFA Information Resources Center, 7500 Security Boulevard, Baltimore, MD 21244-1850 and the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. Copies may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, Suite 400, Arlington, VA 22201-4598.

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devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.

(a) *Standard: qualifications.* The director of a dialysis facility is a qualified physician-director. (See § 405.2102.)

(b) *Standard: responsibilities.* The responsibilities of the physician-director include but are not limited to the following:

(1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;

(2) Assuring adequate training of nurses and technicians in dialysis techniques;

(3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and

(5) When self-dialysis training or home dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48952, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center.

Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and non-medical emergencies.

(a) *Standard: Registered nurse.* The dialysis facility employs at least one full

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time qualified nurse responsible for nursing service. (See § 405.2102.)

(b) *Standard: On-duty personnel.* Whenever patients are undergoing dialysis:

(1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care;

(2) An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and

(3) An adequate number of personnel are readily available to meet medical and nonmedical needs.

(c) *Standard: Self-care dialysis training personnel.* If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (see § 405.2102.)

[41 FR 22511, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, as amended at 43 FR 48953, Oct. 19, 1978; 51 FR 30362, Aug. 26, 1986]

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

The facility must provide dialysis services, as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient.

(a) *Standard: Outpatient dialysis services—(1) Staff-assisted dialysis services.* The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.

(2) *Self-dialysis services.* If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter.